SUMMARY OF AXIS CLINICALS LIMITED AND REGULATORY INSPECTIONS AND APPROVALS (October-2020)

INTRODUCTION:

AXIS Clinicals Limited is a Contract Research Organization for clinical research to support bioequivalence studies and Phase Trials. AXIS Clinicals Limited offers services for Medical writing, Study site support, Bioanalysis, Data management and Statistical services as a one stop full time global CRO to serve the pharmaceutical industry by keeping pace with latest techniques, procedures by ensuring scientific validity of all research projects and complying with global regulations.

AXIS Clinicals Limited is headquartered in Hyderabad, India with operations and facilities in China, Mexico and USA to support the global sponsors. In India, AXIS is having 2 facilities to support bioequivalence studies. Further details were provided under the Table "Legal Identity of the facilities".

Key Features:

- AXIS Clinicals Limited has a total of 9 study areas that have an overall capacity of 330 beds.
- The bioanalytical lab located at head office has equipped with 26 LC-MS/MS and 2 ICP-OES and 1 ICP-MS to support bioanlaytical services.
- Pharmacokinetic analysis and Biostatistical analysis of data will be carried out by using WinNonlin and SAS software's.
- A Clinical Research (CR) and Clinical Data Management (CDM) departments will support phase trails in hospitals and Data management by using Oracle clinical.
- AXIS Clinical Reference Laboratory is approved by NABL as per ISO 15189:2012 and accredited.
- AXIS Clinicals Limited has an Independent Quality Assurance Team and Common Quality Management System across all facilities to have uniform data / conduct of the studies / Documentation / final report preparation.

AXIS Clinicals Limited formerly known as Trident Life Sciences Limited and the scope of the change is only name of the company and has been approved by the Registrar of Companies, Government of India and regulatory agencies like Drug Controller General of India (DCGI) etc.

LEGAL IDENTITY OF THE FACILITIES:

Facility	Address	Scope	Bed capacity	USFDA FEI & DUNS Number
Head office (ACL-01)	AXIS Clinicals Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500049, India.	Clinical, Clinical Reference Lab, Bioanalytical, Pharmacokinetic and Statistical services and Phase trails (Clinical Research), Clinical Data Management (CDM).	192 beds in 4 study areas with bed capacities 62,58,36, 36	FEI No: 3006649033, DUNS No: 86-346-1407
ACL-02 (Operations at this unit were closed from February-2017)	AXIS Clinicals Limited, Plot No. 33 to 35, Alluri Sitaramaraju Nagar, Opp. J.P.N Nagar, Miyapur, Hyderabad, Telangana, 500049, India.	Clinical Phase	128 bed capacities in 4 study areas with bed capacities of 28,36,28 and 36	FEI No: 3010297993, DUNS No: 65-062-3114
ACL-03	AXIS Clinicals Limited, Atharva, Opp. Rajpath club, S.G highway, Bodakdev, Ahmedabad- 380015, Gujarat- India	Clinical Phase	138 bed capacities in 5 study areas with bed capacities of 36,15,15, 36 and 36.	FEI No: 3012359023, DUNS No: 65-100-6277

Note: *The bio-analytical, Pharmacokinetic and biostatistical services will be supported from head office (ACL 01) located in Hyderabad for all the facilities (ACL-01, ACL-02 & ACL-03).*

REGULATORY INSPECTIONS AND ACCREDITATIONS:

AXIS Clinicals Limited conducted bioequivalence studies to support marketing authorization for various regulated markets including US FDA, UK-MHRA, AEMPS-Spain, INFARMED-Portugal, ANSM-France, Turkey-MOH, WHO, DCGI, Health Canada, Thai-MOPH, NPRA-Malaysia, GCC Gulf, MCC-South Africa, MHSD-RoK Kazakhstan etc. for various sponsors. Our facility has been audited and approved by various global regulatory agencies and accreditation bodies and the details were described in the following table.

US-FDA REGULATORY INSPECTIONS:

S.No.	Year	Inspection dates	Scope	Facility	Outcome	Receipt of EIR	Remarks
1	2008	05th-14th Mar 2008	All Phases	ACL-01	Form 483 issued	Yes	Nil
2	2008	27th-31st Oct 2008	All Phases	ACL-01	Form 483 issued	Yes	Nil
3	2009	26th-30th Oct 2009	All Phases	ACL-01	No Form 483	Yes	Nil
4	2010	31st May-11th Jun 2010	Clinical Phase	ACL-01	No Form 483	Yes	Nil
5	2011	14th-16th Feb 2011	Clinical Phase	ACL-02	No Form 483	Yes	Nil
6	2011	16th-21st Mar 2011	Bioanalytical	ACL-01	Form 483 issued	Yes	Nil
7	2011	10th-14th Oct 2011	Clinical Phase	ACL-01	No Form 483	Yes	Nil
8	2012	01st-05th Oct 2012	Clinical Phase	ACL-01	Form 483 issued	Yes	Nil
9	2013	06th-08th Aug 2013	All Phases	ACL-01	No Form 483	Yes	Nil
10	2014	10th-20th Mar 2014	Clinical Phase	ACL-02	No Form 483	Yes	Head office address captured in EIR
11	2016	16th-18th Mar 2016	Bioanalytical (GMP) Phase	ACL-01	Form 483 issued	No	Analytical services with ICP-OES
12	2016	06th-10th Jun 2016	Bioanalytical Phase	ACL-01	Form 483 issued	Yes	Nil
13	2016	11th-21st Jul 2016	Clinical Phase	ACL-01	No Form 483	Yes	Nil
14	2016	11th-25th Aug 2016	Clinical Phase	ACL-02	No Form 483	Yes	Nil
15	2018	21st -25th May 2018	Clinical Phase	ACL-03	No Form 483	Yes	Unannounced Inspection
16	2018	27th – 30th Aug 2018	Bioanalytical Phase	ACL-01	No Form 483	Yes	Unannounced Inspection
17	2018	29th Oct – 05th Nov 2018	Clinical Phase	ACL-01	No Form 483	Yes	Nil

US-FDA REGULATORY INSPECTIONS – CR STUDIES (PATIENT POPULATION STUDIES):

S.No.	Year	Inspection dates	Scope / Therapeutic Indication	Facility	Outcome	Receipt of EIR	Remarks
1	2012	28th May to 01st Jun 2012	Clinical Phase / Epilepsy	AXON Hospital, Hyderabad, Telangana, India	No Form 483	No	Nil
2	2012	04th to 08th Jun 2012	Clinical Phase / Epilepsy	St.Theresa's General Hospital, Hyderabad, Telangana, India	Form 483 issued	No	Nil
3	2016	28th Nov to 02nd Dec 2016	Clinical Phase / IBS with Constipation	M.V.Hospital & Research Centre, Lucknow, Uttar Pradesh, India	Form 483 issued	No	Nil
4	2017	13th to 17th Feb 2017	Clinical Phase / IBS with Constipation	Inamdhar Hospital, Pune, Maharashtra, India	No Form 483	No	Form FDA 484 issued
5	2017	27th Feb to 3rd Mar 2017	Clinical Phase / IBS with Constipation	Gandhi Hospital, Hyderabad, Telangana, India	Form 483 issued	No	Nil
6	2017	17th to 21st Apr 2017	Clinical Phase / IBS with Constipation	Samvedana Hospital, Varanasi, Uttar Pradesh, India	No Form 483	No	Form FDA 484 issued
7	2017	06th to 10th Nov 2017	Clinical Phase/ Psoriasis / Rheumatoid Arthritis	Rathi Hospital, Ahmedabad, Gujarat, India	No Form 483	Yes	Form FDA 484 issued
8	2017	13th to 17th Nov 2017	Clinical Phase / Schizophrenia	Ratandeep Multispeciality Hospital, Ahmedabad, Gujarat, India	No Form 483	No	Form FDA 484 issued
9	2019	04th to 08th Feb 2019	Clinical Phase / Iron Deficiency Anemia	KRM Hospital and Research centre,Lucknow,UP-226010,India.	Form 483 issued	No	Nil
10	2019	05th to 07th Mar 2019	Diarrhea caused by Giardia lamblia	The Grant Government Medical College, Mumbai Central, Mumbai, Maharashtra, India	No Form 483	Yes	Nil
11	2019	09th to 19th Jul 2019	Clinical Phase / Iron Deficiency Anemia	Bodyline Hospitals Pvt. Ltd., Ahmedabad, Gujarat, India	Form 483 issued	No	Form FDA 484 issued
12	2019	11th to 14th Sep 2019	Clinical Phase / Schizophrenia	Shri Hathkesh Healthcare Foundation, Junagadh, Gujarat, India	No Form 483	No	Form FDA 484 issued
13	2019	16th to 19th Sep 2019	Clinical Phase / Iron Deficiency Anemia	Baroda Medical College, Vadodara, Gujarat, India	No Form 483	No	Form FDA 484 issued
14	2019	23rd to 26th Sep 2019	Clinical Phase / Iron Deficiency Anemia	Nirmal Hospital Pvt.Ltd, Surat, Gujarat, India	No Form 483	No	Form FDA 484 issued
15	2019	23rd to 27th Sep 2019	Clinical Phase / Iron Deficiency Anemia	ACSR Govt. Medical College, Nellore, Andhra Pradesh, India	Form 483 issued	No	Form FDA 484 issued
16	2019	04th to 08th Nov 2019	Diarrhea caused by Giardia lamblia	Supe Heart and Diabetes Hospital and Research Centre Nashik, Maharashtra, India.	Form 483 issued	No	Nil
17	2020	02nd to 06th Mar 2020	Schizophrenia	Anand Multispeciality Hospital and Research Centre, Gandhi Nagar, Gujarat, India	Form 483 issued	No	Form FDA 484 issued

OTHER REGULATORY INSPECTIONS:

S.No.	Year	Inspection dates	Scope	Facility	Outcome	Remarks
ANVISA- Brazil						
1	2007	06th-10th Aug 2007	All Phases	ACL-01	Approved	Nil
2	2009	12th-16th Oct 2009	All Phases	ACL-01	Approved	Nil
3	2011	05th-06th Aug 2011	All Phases	ACL-01	Approved	Nil
4	2012	17th-19th Oct 2012	All Phases	ACL-01	Approved	Nil
5	2013	05th-08th Aug 2013	All Phases	ACL-01	Approved	Nil
6	2014	02nd-04th Jun 2014	All Phases	ACL-01	Approved	Nil
7	2015	02nd-04th Mar 2015	All Phases	ACL-01	Approved	Nil
8	2017	07th – 11th Aug 2017	All Phases	ACL-01	Successfully completed	Validity till 03rd Jan 2019
UK-MHRA						
1	2009	24th-27th Feb 2009	All Phases	ACL-01	Approved	GCP Certificate Issued
2	2011	17th-18th Oct 2011	Clinical Phase	ACL-01	Approved	Certificate Issued
3	2014	01st-05th Sep 2014	All Phases	ACL-01	Approved	Nil
4	2018	04th – 08th Jun 2018	All Phases	ACL-01	Approved	Inspection includes the review of Patient Population study.

OTHER REGULATORY INSPECTIONS:

S.No.	Year	Inspection dates	Scope	Facility	Outcome	Remarks
ANSM-France						
1	2009	02nd-03rd Jun 2009	Clinical Phase	ACL-01	Accepted Compliance	Nil
MOH-Turkey						
1	2011	18th-19th Dec 2011	All Phases	ACL-01	Approved	GCP Certificate issued
Thailand-BLQS-GLP Inspection						
1	2014	21st-25th Jan 2014	Bioanalytical	ACL-01	Approved	GLP Certificate issued
WHO						
1	2015	17th-20th Mar 2015	All Phases	ACL-01	Approved	Nil
2	2017	18th-21st Dec 2017	All Phases	ACL-01	Approved	Nil
GCC-DR (Gulf Central Committee for Drug Registration)						
1	2016	15th-16th Feb 2016	All Phases	ACL-01 & 02	Approved	Nil
MCC (Medicines Control Council) – South Africa						
1	2017	25th – 27th Mar 2017	Clinical Phase	ACL-01	Approved	Nil
NPRA (National Pharmaceutical Regulatory Agency) – Malaysia						
1	2018	18th – 22nd Jun 2018	All Phases	ACL-01	Approved	Nil
INFARMED (Portuguese National Authority of Medicines and Health Products)						
1	2018	18th – 20th Jun 2018	Clinical Phase	ACL-03	Approved	Nil
AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) – Spain						
1	2018	17th – 21st Dec 2018	Clinical Phase	ACL-03	Approved	Nil

DCGI INSPECTIONS:

S.No.	Year	Inspection dates	Scope	Facility	Approval Date	Remarks
1	2006	16th Dec 2006	All phases	ACL-01&02	08th Feb 2008	Approved
2	2010	13th -14th Jul 2010	All phases	ACL-01&02	Nil	Compliance submitted & accepted
3	2013	18th-20th Sep 2013	All phases	ACL-01&02	11th Nov 2014	Approved
4	2015	16th-17th Oct 2015	All phases	ACL-01&02	16th Mar 2016	Approved
5	2016	19th Apr 2016	Clinical Phase	ACL-03	01st Aug 2016	Approved
6	2016	22nd-23rd Aug 2016	All phases	ACL-01	Nil	Nil
7	2017	08th Jun 2017	All phases	ACL-01	09th Aug 2017	Approved (Validity till 08th Aug 2020)
8	2019	17th Jul 2019	Clinical Phase	ACL-03	12th Sep 2019	Approved (Validity till 11th Sep 2024)
9	2020	03rd to 04th Jun 2020	All phases	ACL-01	23rd Jul 2020	Approved (Validity till 22nd Jul 2025)

Note: *Details of DCGI inspections for facility approval for conducting bioequivalence studies and clinical research with a notification/ inspection report/approval were listed here.*

ACCREDITATIONS:

S.No.	Year	Inspection dates	Scope	Facility	Outcome	Remarks
NABL						
1	2006	27th Dec 2006	Pre-Assessment	ACL-01	NAP	Nil
2	2007	15th-16th Jan 2007	Assessment	ACL-01	Approved	Nil
3	2008	28th-29th Jun 2008	Surveillance	ACL-01	Approved	Nil
4	2009	07th-08th Mar 2009	Reassessment	ACL-01	Approved	Nil
5	2010	Aug 2010	Desk top audit	ACL-01	Approved	Nil
6	2011	11th-12th Jun 2011	Reassessment	ACL-01	Approved	Nil
7	2012	Aug 2012	Desk top audit	ACL-01	Approved	Nil
8	2013	11th-12th May 2013	Reassessment	ACL-01	Approved	Nil
9	2014	Jul 2014	Desk top audit	ACL-01	Approved	Nil
10	2015	30th-31st May 2015	Reassessment	ACL-01	Approved	Nil
11	2016	01st Aug 2016	Desk top audit	ACL-01	Approved	Nil
12	2017	27th & 28th May 2017	Reassessment	ACL-01	Approved	Nil
13	2018	21st Jun 2018	Desk top audit	ACL-01	Approved	Nil
14	2019	14th & 15th May 2019	Reassessment	ACL-01	Successfully Completed	Nil
15	2020	25th Jul 2020	Desk top audit	ACL-01	Approved	Nil